ALCOHOLD SECTION



# UNITED STATES DEPARTMENT (OF COMMERCE Patent and Trademark Office)

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APPLICATION NO. TELLING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET, NO. 2007/3847, 248 0427/067/95 ALTZUN M 3495, 00085-087

18N2/0917 FINNEGAN HENDERSON FARABOW GARRETT AND DUNNER 1300 I STREET NW WASHINGTON DC 20005-3315 EXAMINER PARKIN, J

ART UNIT PAPER NUMBER

DATE MAILED: 09/17/97

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

PTO-90C (Rev. 2/95)

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1- File Copy

# Office Action Summary

Application No. 08/384,248 Applicant(s)

Alizon et al.

Examiner

Jeffrey S. Parkin, Ph.D.

Group Art Unit 1813



⊠ Responsive to communication(s) filed on 2 Jul 1997	·
X This action is FINAL.	
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.	
A shortened statutory period for response to this action is set to expire3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).	
Disposition of Claims	·
	is/are pending in the application.
Of the above, claim(s) 26-31	is/are withdrawn from consideration.
☐ Claim(s)	is/are allowed.
Claim(s)	
☐ Claims	
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing Re	eview, PTO-948.
☐ The drawing(s) filed on is/are objected	to by the Examiner.
☐ The proposed drawing correction, filed on	isapproveddisapproved.
☐ The specification is objected to by the Examiner.	
$\hfill\Box$ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).	
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been	
☐ received.	
received in Application No. (Series Code/Serial Number)	
$\square$ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).	
*Certified copies not received:	
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s)	
☐ Notice of References Cited, PTO-892	
Information Disclosure Statement(s), PTO-1449, Paper No(s)	·
☐ Interview Summary, PTO-413	<b>\</b>
□ Notice of Draftsperson's Patent Drawing Review, PTO-948	
☐ Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

 Serial No.: 08/384,248
 Docket No.: 3495.0008-08

 Applicants: Alizon et al.
 Filing Date: 02/06/95

#### Response to Amendment

#### Status of the Claims

1. Acknowledgement is hereby made of the amendment filed July 02, 1997, wherein claims 23, 32, and 33 were amended. Claims 23, 32, and 33 are pending in the application while claims 26-31 have been withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. This application contains claims 26-31 drawn to an invention non-elected without traverse in paper no. 5. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01).

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2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### 35 U.S.C. § 103(a)

- 3. The previous rejection of claims 23, 32, and 33 under 35 U.S.C. \$ 103(a) as being unpatentable over Luciw *et al.* (1992), is hereby withdrawn in response to applicants' amendment.
- 4. Claims 23, 32, and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hobson et al. (1985) in view of Hurn et al. (1980). As previously set forth in paper no. 24, applicants submitted the teachings of Wain-Hobson et al. (1985) as evidence that the full-length 9193-nucleotide sequence, and corresponding gag, pol, and env coding regions, of the LAV λ-J19 molecular clone were available to the skilled artisan (refer to figure 1, pages 10-12 and table 1, page 12). Applicants further submit that methods for the production of viral antigens encoded from the claimed restriction fragments, as well as methods for the production and recovery of

antibodies were readily available in the art (refer to page 3 of paper no. 23 and the teachings of Hurn et al., paper no. 20, The examiner concurs that the availability of the respectively). complete nucleotide sequence of the  $\lambda$ -J19 proviral clone would enable the skilled artisan to produce viral antigens from the claimed restriction fragments. However, since this information did not become available to the skilled artisan until January, 1985, and was not disclosed in those applications filed prior to this date (e.g., U.S. serial no. 06/558,109, filed December 05, 1983, and U.K. serial no. 8423659, filed September 19, 1984), priority cannot be extended to those applications filed prior to this date. Accordingly, in view of applicants' submission, the priority date of the instantly claimed invention will be extended to the filing date of serial no. 06/706,562, filed February 28, 1985. Applicants traverse and submit that the deposit date of plasmid  $\lambda$ -J19 is immaterial as it pertains to enabling an earlier filing date. Applicants argue that the disclosure provides a restriction map of the  $\lambda$ -J19 clone. However, applicants have not provided any evidence demonstrating that they were in possession of the complete nucleotide sequence of this clone. Absent evidence to the contrary, priority cannot be extended past the February 28, 1985, filing date.

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Applicants further submit that the prior art does not disclose the nucleic acid fragments claimed by applicants or the motivation to make said fragments. Applicants' arguments have been thoroughly considered but they are not deemed to be persuasive. The Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 U.S.P.Q. 607 (C.C.P.A. 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole

would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 U.S.P.Q. 209 (C.C.P.A. 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 U.S.P.Q. 545 (C.C.P.A.) 1969.

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As previously set forth, Hobson et al. (1985) teach the complete 9193-nucleotide sequence of the lymphadenopathy-associated virus (LAV) (refer to figure 1, pages 10-12). This sequence was derived from a phage  $\lambda$ -J19 proviral clone that appears to be identical to that disclosed by applicants. The location, size, and coding potential of several viral genes including gag, pol, and env were identified. This teaching does not recite the precise restriction fragments claimed by applicants or methods for the generation of immunological reagents.

Hurn et al. (1980) provide art-recognized methods for the generation of immunological reagents (e.g., polyclonal and monoclonal antibodies). The authors describe, inter alia, immunogen preparation, adjuvant selection, immunization routes and dosing, hybridoma selection and preparation, and antibody isolation and purification. This teaching does not disclose any HIV restriction fragments.

However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to employ  $\lambda$ -J19 restriction fragments corresponding to the *gag*, *pol*, and *env* coding regions as disclosed by Hobson *et al*. (1985), to express HIV-1 viral antigens and employ these antigens in art-recognized methods for the production of HIV-1-specific antibodies, as taught by Hurn *et al*. (1980). These antibodies would be of obvious clinical and diagnostic import.

#### 37 C.F.R. § 1.129(a)

5. Since the fee set forth in 37 C.F.R. § 1.17(r) for a first

submission subsequent to a final rejection has been previously paid, applicant, under 37 C.F.R. § 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 C.F.R. § 1.17(r) are filed prior to the filing of an appeal brief under 37 C.F.R. § 1.192. Upon the timely filing of a second submission and the appropriate fee of \$ for a entity under 37 C.F.R. § 1.17(r), the finality of the previous Office action will be withdrawn. notice of appeal and the appeal fee set forth in 37 C.F.R. § 1.17(e) were filed prior to or with the payment of the fee set forth in 37 C.F.R. § 1.17(r), the payment of the fee set forth in 37 C.F.R. § 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 C.F.R. § 1.129(a). view of 37 C.F.R. § 132, no amendment considered as a result of payment of the fee set forth in 37 C.F.R. § 1.17(r) may introduce new matter into the disclosure of the application.

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## Finality of Office Action

6. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

### Correspondence

7. Correspondence related to this application may be submitted to Group 1813 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Group 1813 is (703) 305-

7939. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

8. Any inquiry concerning this communication should be directed to **Jeffrey S. Parkin**, **Ph.D.**, whose telephone number is **(703)** 308-2227. The examiner can normally be reached Monday through Friday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, **Donald E. Adams**, **Ph.D.**, can be reached at **(703)** 308-0570. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1813 receptionist whose telephone number is **(703)** 308-0196.

Respectfully,

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Jeffrey S. Parkin, Ph.D.

Patent Examiner Art Unit 1813

April 11, 1997

LAURIE A. SCHEINER
PATENT EXAMINER
GROUP 1800